

§ 1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) The drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient listed in paragraph (e) of this section have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–3, 830, and 957–8) to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No exemption granted pursuant to § 1310.14 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in drug product compositions: Any change in the quantitative or qualitative composition of an exempt drug product listed in paragraph (d) requires a new application for exemption.

(d) In addition to the drug products listed in the compendium set forth in § 1310.01(f)(1)(iv)(A), the following drug products, in the form and quantity listed in the application submitted (indicated as the “date”) are designated as exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS CONTAINING EPHEDRINE AND THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ANOTHER ACTIVE MEDICINAL INGREDIENT

Supplier	Product name	Form	Date
[Reserved]

[60 FR 32463, June 22, 1995]

PART 1311—REGISTRATION OF IMPORTERS AND EXPORTERS OF CONTROLLED SUBSTANCES

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AUTHORITY: 21 U.S.C. 952, 956, 957, 958, unless otherwise noted.

SOURCE: 36 FR 7812, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1311.01 Scope of Part 1311.

Procedures governing the registration of importers and exporters of controlled substances pursuant to sections